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#5 1648

Attorney's Docket No.: 00088-008004 / 092CIP-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Philip R. Andersen, et al. Art Unit : 1648
Serial No. : 09/963,759 Examiner : Budens, R.
Filed : September 25, 2001
Title : DIAGNOSTIC DEVICE USING GP40

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the specification:

Please delete the paragraph beginning at page 24 line 25 and ending with page 24 line 31.

At page 5, lines 16-18, delete the sentence "Fig. 5 is the...nucleic acid."

At page 25, line 6 add --12301 Parklawn Drive, Rockville, MD 20852-- immediately after "ATCC".

In the claims:

Cancel claims 1-13.

Add claims 14-24 to read as follows.

--14. A method for detecting antibody to FIV in a sample comprising:

providing an isolated Feline Immunodeficiency Virus (FIV) envelope polypeptide that reacts specifically with a monoclonal antibody that is specific for the FIV envelope protein gp130; and

detecting a reaction between the polypeptide and antibody in the sample.--

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

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--15. The method of claim 14 in which the envelope polypeptide is the FIV transmembrane envelope protein (gp40).—

--16. The method of claim 15 in which the envelope polypeptide is recombinant gp40.--

--17. The method of any one of claims 14-16 in which the reagent comprises a binding moiety that binds to sample antibody reacted with the polypeptide.--

--18. The method of claim 17 in which the binding moiety is attached to a color-producing moiety.--

--19. An assay device for detecting antibody to FIV in a sample comprising:

an isolated Feline Immunodeficiency Virus (FIV) envelope polypeptide that reacts specifically with a monoclonal antibody that is specific for the FIV envelope protein gp130; and

at least one reagent for detecting a reaction between the polypeptide and antibody in the sample.--

--20. The device of claim 19 in which the envelope polypeptide is the FIV transmembrane envelope protein (gp40).—

--21. The device of claim 20 in which the envelope polypeptide is recombinant gp40.--

--22. The device of any one of claims 19-21 in which the reagent comprises a binding moiety that binds to sample antibody reacted with the polypeptide.--

--23. The device of claim 22 in which the binding moiety is attached to a color-producing moiety.—

--24. An ELISA assay device for detecting antibody to FIV in a sample comprising:

a capture protein consisting essentially of recombinant gp40; and

at least one reagent for detecting a reaction between the capture protein and antibody in the sample.--

In the abstract:

Replace the abstract with the following version.

-- Assay methods and devices for detecting antibodies to Feline Immunedeficiency Virus (FIV) using an FIV envelope polypeptide such as recombinant gp40.--

In the drawings:

Formal drawings are submitted herewith, with the exception of Fig. 5 which has been canceled.

REMARKS

This preliminary amendment presents claims to methods and devices for detecting feline immune deficiency virus (FIV) in a sample by detecting FIV antibodies in the sample that bind to FIV envelope proteins. The claims are limited to the use of the FIV polypeptides defined in the allowed claims in parent application USSN 08/852,143, filed May 6, 1997.

Basis for the amendment appears at: a) page 3 lines10-19 disclosing purified FIV envelope proteins, including gp40 and gp130; and b) page 3, lines 20-29 disclosing assays for detecting antibodies to FIV using the purified polypeptides described at lines 10-19, above. Additional details for performing such immunoassays appear in the specification at pages 9:6-30; page 10:2 through 11:23; and page 19:18 et seq.

Accompanying this preliminary amendment are: a) an information disclosure statement; and b) transmittal of formal drawings. The sequences contained in this application have been deleted, and, therefore, the requirement to comply with 37 CFR 1.821-1.825 is moot. A property rights statement in response to the Notice mailed December 13, 2001 was filed under separate cover on January 25, 2002.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be examined. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 1/29/02

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Version with markings to show changes made

In the claims:

Claims 1-14 have been cancelled.

New claims 14-24 have been added as follows:

--14. A method for detecting antibody to FIV in a sample comprising:

providing an isolated Feline Immunodeficiency Virus (FIV) envelope polypeptide that reacts specifically with a monoclonal antibody that is specific for the FIV envelope protein gp130; and

detecting a reaction between the polypeptide and antibody in the sample.--

--15. The method of claim 14 in which the envelope polypeptide is the FIV transmembrane envelope protein (gp40).—

--16. The method of claim 15 in which the envelope polypeptide is recombinant gp40.--

--17. The method of any one of claims 14-16 in which the reagent comprises a binding moiety that binds to sample antibody reacted with the polypeptide.--

--18. The method of claim 17 in which the binding moiety is attached to a color-producing moiety.--

--19. An assay device for detecting antibody to FIV in a sample comprising:

an isolated Feline Immunodeficiency Virus (FIV) envelope polypeptide that reacts specifically with a monoclonal antibody that is specific for the FIV envelope protein gp130; and

at least one reagent for detecting a reaction between the polypeptide and antibody in the sample.--

--20. The device of claim 19 in which the envelope polypeptide is the FIV transmembrane envelope protein (gp40).—

--21. The device of claim 20 in which the envelope polypeptide is recombinant gp40.--

--22. The device of any one of claims 19-21 in which the reagent comprises a binding moiety that binds to sample antibody reacted with the polypeptide.--

--23. The device of claim 22 in which the binding moiety is attached to a color-producing moiety.—

--24. An ELISA assay device for detecting antibody to FIV in a sample comprising:

a capture protein consisting essentially of recombinant gp40; and

at least one reagent for detecting a reaction between the capture protein and antibody in the sample.--

In the abstract:

[A purified polypeptide having an epitope of an antigenic polypeptide of FIV] Assay methods and devices for detecting antibodies to Feline Immunedeficiency Virus (FIV) using an FIV envelope polypeptide.